REMARKS

Claims 20-34 are pending in the application. By this amendment claims 28-31 have been cancelled without prejudice or disclaimer. The cancellation of the rejected claims reduces the issues and places the present application in condition for allowance. No new matter has been introduced. Accordingly, entry of the amendment is respectfully requested.

Applicants gratefully acknowledge that the Examiner has rejoined all claims and has allowed claims 20-27 and 32-34, which constitute all pending claims upon entry of this amendment.

Information Disclosure Statement

Applicants gratefully acknowledge receipt of the initialed form PTO-1449 submitted with the Supplemental Information Disclosure Statement which was filed on January 28, 2010.

Priority Documents

Applicants again request that the Examiner acknowledge receipt of **all** of the certified copies of the Japanese priority documents. As discussed in the previous response, the USPTO online database (PAIR) indicates that the certified copies of the two

Japanese Priority documents (JP2004-068229, filed March 10, 2004, and JP2004-350599 filed December 3, 2004) are in the file.

The Examiner is thanked for withdrawing the rejection of the claims under 35 U.S.C. 102(a) as being anticipated by Yamazaki et al (WO2004/02469, published 3/25/047) and, in connection therewith, for making the determination of support and benefit of priority of the priority document JP2004-068229, filed March 10, 2004, in view of the English translation thereof submitted with the previous response.

The Restriction Requirement

The Examiner is thanked for reconsidering the restriction requirement and for rejoining all of the claims.

Rejection Under 35 U.S.C. 112, first paragraph - Enablement

Claims 28-31 are rejected under 35 U.S.C. 112 first paragraph, on the grounds that the specification does not reasonably provide enablement for a drug which can teat the myriad of conditions encompassed by the instant claims. This rejection is respectfully traversed.

The Office Action maintains that the specification does not enable one ordinarily skilled in the art to practice the claimed invention because undue experimentation would be required to determine which of the many types of cancer and rheumatic diseases could

be treated or prevented. However, the specification provides sufficient guidance to enable those skilled in the art practice the invention without undue experimentation. It is clearly disclosed in the specification that the diseases which can be treated are those which are affected by antagonism against the chemokine receptor CXCR4.

The rejection refers to the Wands factors to be considered in determining whether a disclosure would require undue experimentation. In particular, it is noted that these include (1) the quantity of experimentation, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Weighing these factors under the present circumstances demonstrates that the 35 U.S.C. 112, first paragraph, enablement rejection is improper and should be withdrawn. In this regard, (a) the quantity of experimentation for determining if components are covered by the claims would be low following the procedures and criteria fully disclosed in Applicants' specification, (b) there is sufficient direction or guidance presented to practice the claimed method, (c) working examples are provided in that Applicants have provided a number of exemplary compositions useful with their disclosed and claimed methods, (d) the relative skill in the art, the nature of the invention, and the claim language are sufficiently related that undue experimentation would not be required so as to enable the practice of the disclosed and claimed invention.

Applicants are not only entitled to claims that include embodiments set forth as representative species and in their working examples, but claims that are directed to their broader disclosure so as to provide the level of protection that is commensurate with their invention. As stated in In re Angstadt and Griffin, 537 F.2d 498, 190 USPQ 214 (CCPA 1976), at page 218:

> Appellants have apparently not disclosed *every* catalyst which will work; they have apparently not disclosed *every* catalyst which will not work. The question, then, is whether in an unpredictable art, section 112 requires disclosure of a test with *every* species covered by a claim. To require such a complete disclosure would apparently necessitate a patent application or applications with "thousands" of examples or the disclosure of "thousands" of catalysts along with information as to whether such exhibits catalytic behavior resulting in the production of hydroperoxides. More importantly, such a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments. This would tend to discourage inventors from filing patent applications in an unpredictable area since the patent claims would have to be limited to those embodiments which are expressly disclosed. A potential infringer could readily avoid "literal" infringement of such claims by merely finding another analogous catalyst complex which could be used in "forming hydroperoxides".

As in In re Angstadt and Griffin, Applicants have provided sufficient guidance for one having ordinary skill in the art to make and use Applicants' invention. Thus, without undue experimentation or effort or expense, components that are within the scope of the invention can be determined. Conversely, without undue experimentation or effort or expense, components that are not within the scope of the invention can be determined,

and, of course, and as stated in In re Angstadt and Griffin, nobody will use them and the claims do not cover them.

Further, as stated in In re Angstadt and Griffin, the term "experimentation" does not require that the guidance be sufficient to enable one skilled in the art to determine with reasonable certainty before performing the reaction, whether a claimed product will be obtained. To do so would negate any experimentation because the term "experimentation" implies that the success of the particular activity is uncertain. Here, with the guidance provided in the originally filed application with respect to the characteristics disclosed therein, any experimentation required would not be undue and certainly would not "require ingenuity beyond that to be expected of one of ordinary skill in the art." In re Angstadt and Griffin citing Fields v. Conover, 170 USPQ 276, 279 (CCPA 1971).

Moreover, Applicants point out that the inclusion of a number of representative examples is not required by the patent statute, and is not an end in themselves. Rather, they are a means by which certain requirements of the statute may be satisfied. Thus, Applicants' inclusion of a number of representative examples in the instant specification is one way of demonstrating the operability of their broader invention, as well as teaching how to make and use the broader invention. However, Applicants should not be limited thereto, when they have in their originally presented specification and claims established

the broader intent of their invention. As stated in In re Wands, 8 U.S.P.Q.2d 1400, 1404 (CAFC 1988):

> Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. "the key word is 'undue,' not 'experimentation.'

Determining which particular type of disease could be treated is guided by the disclosure of antagonism against the chemokine receptor CXCR4, and the experimentation would involve routine screening. Thus, Applicants have established that their invention is enabling for one having ordinary skill in the art to practice their claimed subject matter without undue experimentation, and the rejection should be withdrawn.

In any event, to advance prosecution applicants have cancelled rejected claims 28-31 without prejudice or disclaimer to place the application in condition for allowance.

Reconsideration and withdrawal of the rejection is respectfully requested.

Double Patenting Rejections

Applicants gratefully acknowledge the Examiner's withdrawal of the double patenting rejections over commonly assigned U.S. Patent No. 7,176,227 to Yamazaki et al and commonly assigned copending U.S. Patent Application No. 11/704,860.

CONCLUSION

For the reasons discussed above, it is respectfully submitted that this application is in condition for allowance and the rejections should be withdrawn. Favorable consideration with early allowance of the application is most earnestly requested.

If the Examiner has any questions, or wishes to discuss this matter, please call the undersigned at the telephone number indicated below.

While it is believed that no fees are due with this amendment, the U.S. Patent and Trademark Office is hereby authorized to charge any fees which may be deemed necessary to Deposit Account No. 19-0089 (MOEG-P100 P33287).

Respectfully submitted,
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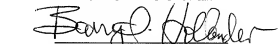

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